

# OFFICE OF AUDITS & ADVISORY SERVICES



## CONTROLLED SUBSTANCES – HHSA EDMOOR SKILLED NURSING FACILITY

### *FINAL AUDIT REPORT*

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July 17, 2013

TO: Alfredo Aguirre, Division Director  
HHSA – Behavioral Health Services

FROM: Juan R. Perez  
Chief of Audits

### FINAL REPORT: CONTROLLED SUBSTANCES – HHSA EDGEMOOR SKILLED NURSING FACILITY

Enclosed is our report on the Controlled Substances – HHSA Edgemoor Skilled Nursing Facility Audit. We have reviewed your responses to our recommendations and have attached them to the audit report.

Thank you for the courteousness and cooperation extended to the Office of Audits & Advisory Services during the course of the audit.

If you have any questions, please contact me at (858) 495-5661.

**JUAN R. PEREZ**  
Chief of Audits

AUD:TF:aps

Enclosure

c: Nick N. Macchione, Director, HHSA  
Tracy M. Sandoval, Deputy Chief Administrative Officer/Auditor and Controller  
Dean Arabatzis, Chief Operations Officer, HHSA  
Andrew Pease, Executive Finance Director, HHSA

## INTRODUCTION

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### **Audit Objective**

The Office of Audits & Advisory Services (OAAS) completed an audit of Controlled Substances at the Health and Human Services Agency's Edgemoor Skilled Nursing Facility (Edgemoor). The objective of the audit was to verify that adequate controls exist over the purchase, storage, and use of controlled substances.

### **Background**

Edgemoor operates in conjunction with the County of San Diego Psychiatric Hospital. The facility provides long term medical care to patients with complex medical needs. Edgemoor operates a pharmacy which is responsible for dispensing medications, including controlled substances to the nursing stations based on medical prescriptions. In addition, the pharmacy is responsible for purchasing, storing, and disposing of unusable<sup>1</sup> medications.

The use and possession of controlled substances is regulated by the Controlled Substance Act (CSA) of 1970, which is primarily enforced by the Drug Enforcement Administration (DEA). Title 21 of the Code of Federal Regulations (CFR) outlines controlled substance regulations for the enforcement of the CSA.

Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules based on their potential for abuse, medical use, and safety or dependence liability.<sup>2</sup> The DEA has strict requirements for record keeping, inventory, security, and handling of controlled substances.

Edgemoor has established policies related to controlled substances that outline protocols and practices for activities such as receipt, storage, inventory, and disposal of expired and unusable drugs.

### **Audit Scope & Limitations**

The scope of the audit focused on Schedule II Controlled Substances (controlled substances) administered at Edgemoor's pharmacy and nursing stations. OAAS evaluated data from FY 2010-11 to present.

This audit was conducted in conformance with the International Standards for the Professional Practice of Internal Auditing prescribed by the Institute of Internal Auditors as required by California Government Code, Section 1236.

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<sup>1</sup> Unusable medications include controlled substances that have been expired, recalled, and wasted (e.g., patient refuses to take or spit out, spillage, breakage, etc.).

<sup>2</sup> Schedule I Controlled Substances have no currently accepted medical use in the United States; Schedule II Controlled Substances have a high potential for abuse which may lead to severe dependence; Schedule III-V Controlled Substances have a less potential for abuse than Schedule II.

**Methodology**

OAAS performed the audit using the following methods:

- Reviewed applicable Federal and State laws and regulations.
- Examined Edgemoor policies and procedures related to controlled substances.
- Evaluated Edgemoor's controls over the safeguarding and recordkeeping of their controlled substances.
- Assessed compliance with key requirements and internal policies.
- Interviewed personnel on policies and processes regarding controlled substances.
- On a sample basis, conducted specific audit procedures, such as direct observation, inspections, reconciliations, recalculations, and data analysis of processes relevant to the administration of controlled substances.

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**Summary**

Within the scope of the audit, there is reasonable assurance that adequate controls exist over the purchase, storage, and use of controlled substances. Further, OAAS did not find instances of controlled substances being lost, unaccounted for, or diverted. However, we noted the following exceptions:

**Finding I:****Controls Over the Disposal Process of Controlled Substances Need Improvement**

Audit work identified the following control weaknesses related to the disposal of controlled substances at Edgemoor's Pharmacy:

- **Expired Controlled Substances Are Not Sent for Destruction in a Timely Manner**

Expired and unusable controlled substances are set aside for accumulation before destruction. Subsequently, these drugs are sent to a reverse distributor for disposal and reporting in accordance with DEA regulations. It takes usually one to two months for the reverse distributor to complete required DEA Forms 222<sup>3</sup> and process disposal requests.

OAAS reviewed a sample of 27 batches of controlled substances removed from inventory due to expiration. Audit work found that shipment to the reverse distributor for 24 of these batches was significantly delayed, as shown in Table 1.

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<sup>3</sup> DEA Form 222 is a paper-based form used to order controlled substances. The DEA Form 222 also allows the exchange of controlled substances from the registrant to another party registered with the DEA (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).

**Table 1. Expired Controlled Substances Accumulation Period**

Batches Shipped for Disposal	Accumulation Period Before Shipment	%
6	1 to 6 months	25%
6	6 months to 1 year	25%
8	1 to 2 years	33%
4	More than 2 years	17%

The remainder three batches of controlled substances had not been shipped to the reverse distributor. While the accumulation period for two of the three batches seemed reasonable, one of the batches had been removed from inventory and awaiting shipment for over six months.

While the DEA does not impose a specific time limit within which controlled substances must be sent to disposal, it is best practice to implement internal policies that establish accumulation period of controlled substances prior to destruction. For example, HHSA Mental Health Services Hazardous Waste Management Policy<sup>4</sup> requires accumulation period of drugs awaiting destruction not to exceed 90 days.

Because there is no DEA regulation, Edgemoor's Controlled Substances existing policy does not delineate specific accumulation period prior to shipment to the reverse distributor. Therefore, it has been common practice that controlled substances awaiting disposal are locked in a cabinet for an undefined period of time before shipment. As a result, the risk of drugs being lost, unaccounted for, or diverted increases.

- **Records of Controlled Substances Awaiting Disposal Were Not Readily Available**

During fieldwork, OAAS' staff observed three cabinets with numerous expired and unusable drugs awaiting shipment to the reverse distributor. At the time, a complete list of controlled substances awaiting disposal was not readily available. During the course of the audit, it came to our attention that staff developed a Pharmacy Stock Narcotic Return Log to maintain records of controlled substances awaiting destruction.

Lack of adequate records related to controlled substances awaiting disposal increases the risk of theft and/or diversion of drugs without anybody noticing. Maintaining records of drugs awaiting disposal that document the specific information such as the type of drug, amount, origin, and date removed from inventory is an indication of a strong system of controls.

<sup>4</sup> HHSA, Mental Health Services, Policy/Procedure No. 02-02-01 Hazardous Waste Management.

**Recommendation:** To strengthen controls over the disposal process of controlled substances, Edgemoor management should:

1. Update the Controlled Substances policy and establish a specific time period of accumulation of controlled substances prior to shipment to the reverse distributor for disposal.
2. Ensure that the Pharmacy Stock Narcotic Return Log is completed when controlled substances are removed from inventory.
3. Consider updating the Pharmacy Stock Narcotic Return Log to include expiration date of controlled substances, if applicable, and the pharmacist's initials.
4. Develop a training plan to properly communicate policy updates and related process changes to staff.

**Finding II: Opportunities Exist for Enhancing Accuracy and Clarity of Controlled Substances Related Records**

While conducting fieldwork at Edgemoor's Pharmacy, OAAS inspected the following records:

- Sample of controlled substances' log books.
- Sample of DEA Forms 222 processed for purchases.
- Log sheets that record the use of DEA Form 222.

We identified various clerical errors in the completion of these records, as well as a lack of clarity. More specifically, we found incorrectly recorded transactions in the log books, significant delay recording a drug purchase, incomplete DEA Forms 222, duplicate recording of the use of a DEA Form 222, and out of sequence transactions.

We also noted that log sheet does not require the date of use to be completed which makes it difficult to verify whether DEA Forms 222 were used in sequential order.

According to Edgemoor staff, the majority of the errors found occurred during a period of high turnover of temporary pharmacists that did not have adequate training.

A strong internal control system involves procedures designed to maintain clear and organized documentation. Absence of clarity and organization of controlled substances records prevents from identifying and reconciling errors in a timely manner, as well as reduces reliability on these records.

**Recommendation:** To ensure that controlled substances records are accurate and complete, Edgemoor management should:

1. Continue providing adequate training to staff to ensure that controlled substances records are clear, thorough, organized, and easy to reconcile.
2. Establish a review process of controlled substances records on a periodic basis to ensure adequacy of records.
3. Revise the DEA Form 222 log sheet to include the date of use.

Office of Audits & Advisory Services

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## **DEPARTMENT'S RESPONSE**



**NICK MACCHIONE, MS, MPH, FACHE**  
DIRECTOR

**County of San Diego**  
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**MICHAEL S. KRELSTEIN, MD**  
CLINICAL DIRECTOR

July 09, 2013

**RECEIVED**

TO: Juan R. Perez, Chief of Audits  
FGG – Auditor and Controller

**JUL 11 2013**

**OFFICE OF AUDITS &  
ADVISORY SERVICES**

FROM: Alfredo Aguirre, Director  
HHSA – Behavioral Health Services

**DEPARTMENT RESPONSE TO AUDIT RECOMMENDATIONS: CONTROLLED  
SUBSTANCES AUDIT - HHSA EDMOOR SKILLED NURSING FACILITY**

**Finding I:** Controls Over the Disposal Process of Controlled Substances Need Improvement

**OAAS Recommendation:** To strengthen controls over the disposal process of controlled substances, Edgemoor management should:

1. Update the Controlled Substances policy and establish a specific time period of accumulation of controlled substances prior to shipment to the reverse distributor for disposal.
2. Ensure that the Pharmacy Stock Narcotic Return Log is completed when controlled substances are removed from inventory.
3. Consider updating the Pharmacy Stock Narcotic Return Log to include expiration date of controlled substances, if applicable, and the pharmacist's initials.
4. Develop a training plan to properly communicate policy updates and related process changes to staff.

**Action Plan:** Edgemoor agrees with the audit findings and has incorporated the following remedies:

- 1) Please see the attached Edgemoor Policy and Procedures (P&P) #1014 on Controlled Drugs. It was updated to include the accumulation and destruction of expired drugs within one year after removing them from the inventory.

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- 2) P&P 1014 incorporated a semi-annual review of the pharmacist's performance in the area of receipt, storage, dispensing and documentation of inventory of records.
- 3) All expired controlled drugs are removed one month ahead of the manufacturer's expiration date and are documented in the inventory book that documents the expiration date. P&P 1014 requires that two pharmacists review the inventory as often as necessary but no less than semi-annually. Therefore, duplication of documentation is unnecessary to include the expiration date in the Return Log.
- 4) The updated P&P # 1014 includes prescribed schedules of tracking and monitoring controlled substances from receipt to disposal. At a minimum, Edgemoor plans to conduct a review at least semi-annually for an evaluation of existing procedures and may develop training based on the result of the evaluation.

**Planned Completion Date:** Implemented

**Contact Information for Implementation:** Grace Tsai, Chief Pharmacist

**Finding II:** Opportunities Exist for Enhancing Accuracy and Clarity of Controlled Substances Related Records

**OAAS Recommendation:** To ensure that controlled substances records are accurate and complete, Edgemoor management should:

1. Continue providing adequate training to staff to ensure that controlled substances records are clear, thorough, organized, and easy to reconcile.
2. Establish a review process of controlled substances records on a periodic basis to ensure adequacy of records.
3. Revise the DEA Form 222 log sheet to include the date of use.

**Action Plan:** Edgemoor Pharmacy agrees with the findings of the audit as we have identified a clerical error rate of less than 0.75% per year.

- 1) Edgemoor P&P 1014 was updated to include the required training for newly hired pharmacist, as well as for on-going trainings for dispensing pharmacists on new policies and procedures.

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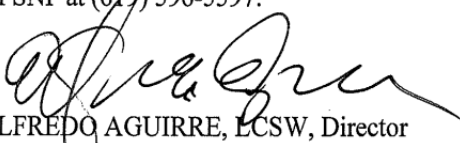
2) The pharmacist's work will be periodically reviewed and monitored by the Chief Pharmacist or their designee at intervals of every six months.

3) Please see the attached revised DEA Form 222 Log Sheet that includes the date of use.

**Planned Completion Date:** Implemented

**Contact Information for Implementation:** Grace Tsai, Chief Pharmacist

If you have any questions, please contact Walter Hekimian, Assistant Deputy Director at Edgemoor DPSNF at (619) 596-5597.

*cm*   
ALFREDO AGUIRRE, LCSW, Director  
Behavioral Health Services

Attachment:

Policy and Procedure #1014

Policy and Procedure #MEDS-008

DEA Form 222 Log Sheet

cc: Dr. Michael Krelstein, BHS Clinical Director  
Cecilia Redondo, Assistant Deputy Director, BHS  
Walter Hekimian, Assistant Deputy Director, Edgemoor DPSNF  
James Lardy, Finance Officer, Fiscal

**OFFICE OF AUDITS & ADVISORY SERVICES'**  
**REPLY TO THE DEPARTMENT'S RESPONSE**

**Finding I - Recommendation 3:** Edgemoor Pharmacy's response stated that the manufacturer's expiration date of controlled substances is documented in the inventory book when the expired drugs are removed. Therefore, duplication of documentation is unnecessary to include the expiration date of controlled substances in the Return Log.

During audit fieldwork OAAS found that, while the inventory book includes the date expired controlled substances are removed from inventory, the manufacturer's expiration date is not recorded. Documentation of the manufacturer's expiration date upon removal will assist Edgemoor's management to effectively monitor disposal of unusable controlled substances and identify unnecessary waste.

**Finding I - Recommendation 4:** Edgemoor Pharmacy's action plan stated that they are planning to conduct a semi-annual review to evaluate existing procedures and may develop training based on the results of the evaluation.

OAAS's recommendation to develop a training plan to properly communicate policy updates and related process changes to staff is intended to ensure that our recommended control improvements over the disposal process are properly and timely communicated to staff.

Edgemoor Pharmacy's action plan stated above does not include the implementation of our recommendation but outlines an alternative solution.

**Finding II:** Edgemoor Pharmacy's response to the finding included a clerical error rate of less than 0.75% per year. This error rate was not determined nor validated by OAAS.